

REMARKS/ARGUMENTS

Claims 1, 19-21, and 23-36 are pending. Claims 2-18 and 22 were previously canceled. All pending claims stand substantively rejected. Reconsideration of the claims is respectfully requested. The paragraph numbering below follows that of the Detailed Action.

It is hoped that the issues in dispute will be overcome or that the issues for appeal will be simplified after the Examiner has had an opportunity to reconsider the claims.

First Rejection Under 35 U.S.C. §102

¶1. Claims 1, 19-24, 28, 29, and 34 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,110,484 to Sierra et al. (“Sierra”). This rejection is traversed. According to MPEP 2131, to anticipate a claim, a cited reference must teach every element of the claim. Sierra fails to meet this test.

Presently pending independent claims 1 and 34 are drawn to a fragmented single phase aqueous colloid.

Sierra Describes A Dried Powder, Not A Fragmented Aqueous Colloid

In contrast to the presently claimed fragmented aqueous colloid, Sierra describes a freeze-dried powder. At col. 8, lines 3-8, Sierra describes forming a gelatin-SPEG gel. The gel is then lyophilized and pulverized. Lyophilization, which is also known as freeze-drying, typically involves freezing a material and reducing the surrounding pressure to allow the frozen water in the material to sublimate from the solid phase to gas. It is a drying process whereby the water is removed. A gel which has been lyophilized is dried and contains no water, and thus is not the same as the presently claimed aqueous colloid.

The Office Action at page 2 states that “The pulverized gelatin of Sierra meets the claim limitations [...] aqueous colloid [...]. With respect to the claim limitation ‘substantially free of free aqueous phase’, the lyophilized and pulverized gelatin is essentially free of water.”

There is no dispute that Sierra’s lyophilized and pulverized gelatin is substantially free of a free aqueous phase (as recited in presently pending claim 1) or that it is not hydrated above its capacity to absorb water (as recited in presently pending claim 34). However, the

lyophilized and pulverized gelatin is **not** an aqueous colloid. It is dry and contains no water. Presently pending independent claims 1 and 34 are drawn to aqueous colloids, and therefore are different from Sierra's lyophilized gelatin.

Sierra Describes A Slurry, Not A Colloid As Claimed

Example 3 of Sierra also describes reconstituting a lyophilate with a Tris buffered saline to form a resultant slurry. However, there is no teaching or suggestion that this resultant slurry includes a fragmented single phase aqueous colloid as presently claimed. It is improper to rely solely on a proposed definition of "colloid," without giving thoughtful consideration to the recited claim terms that characterize the colloid.

The Office Action at page 6 states that "Slurry by definition is a thin watery mixture of a fine insoluble material [...]." The defined term "watery" suggests the presence of a free aqueous phase. In contrast, presently pending claim 1 is drawn to a colloid substantially free of a free aqueous phase. Thus Sierra's slurry, which is watery, does not anticipate the colloid of pending claim 1, which has no free aqueous phase.

Similarly, presently pending claim 34 is drawn to a colloid that is not hydrated above its capacity to absorb water. It is unclear whether Sierra's "fine insoluble material" as proposed by the Office Action is hydrated or unhydrated as it exists in the watery milieu. Absent a showing that Sierra teaches a colloid that is not hydrated above its capacity to absorb water, the rejection is improper. Sierra's slurry does not anticipate the presently claimed colloid.

The Action at page 7 states that Sierra's "gelatin is not present as a dry powder and is instead mixed with the buffer that is aqueous in nature." Regardless, it is the addition of the Tris buffered saline that creates the slurry, as noted in Sierra at col. 8, lines 14-20. The Action's proposed definition of slurry suggests the presence of a free aqueous phase, and provides no guidance as to the degree of hydration. Thus, Sierra's slurry fails to anticipate presently pending independent claims 1 and 34.

The Action at page 7 also states that Sierra's lyophilized and pulverized gelatin is mixed with Tris buffer, which results in an aqueous colloid. Notwithstanding the fact that Sierra describes the resulting mixture as a slurry and not a colloid, there is no showing that Sierra's

mixture of gelatin and Tris forms an aqueous colloid substantially free of a free aqueous phase (as recited in presently pending claim 1), or that Sierra's mixture forms an aqueous colloid that is not hydrated above its capacity to absorb water (as recited in presently pending claim 34). Thus, Sierra's mixture fails to anticipate presently pending independent claims 1 and 34.

Sierra Not Shown To Disclose The Claimed Degradation Rate

As recited in presently pending independent claims 1 and 34, the colloid can have an *in vivo* degradation time of less than one year.

First Alleged Basis for Inherency

The Office Action at page 3 concludes that the degradation rate is inherent to Sierra's pulverized gelatin "because Sierra teaches the preparation of gelatin in the same procedure as in the instant examples." However, Sierra's gelatin is **not** prepared according to the same procedure provided in the instant examples, as shown by the following table. Thus, the Examiner's conclusion is improper.

Example 3 (Instant Application)	Example 3 (Sierra)
Gelatin allowed to swell in distilled water at 1-10% solids (w/w) chilled to 5°C.	Phosphate-buffered saline added to dilute gelatin to a concentration of 15 mg/mL.
Resultant hydrogel fragmented by stirring with an impeller driven by a motor.	SPEG added to gelatin solution for a final concentration of 10 mg/mL.
NaIO ₄ and NaOH added to achieve 0.05M NaIO ₄ and 0.10M NaOH. Held at 0°-8°C for 2-3 days.	Gelatin-SPEG solution allowed to cool to room temperature and gel.
Fragments washed with 5°C water to achieve pH 8.	Gel lyophilized and pulverized by grinding mill.
Fragments washed with aqueous buffer and left at 0°-8°C to equilibrate with buffer.	
Free buffer decanted.	

The requirements for a rejection based on inherency are well established, and any rejection under inherency must follow these guidelines. As set out in MPEP 2112, in procedural terms the initial burden is on the Examiner to provide rationale or evidence tending to show inherency. MPEP 2112 (IV) provides the following guidance regarding inherency.

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be

established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' "; and
" "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

It has not been shown that the presently claimed degradation time **must** flow as a natural consequence from the technological constraints of Sierra, and thus the conclusion of the inherency rejection is improper.

Second Alleged Basis for Inherency

The Action at page 7 asserts that the process (i.e. species) described by Sierra reads on the process steps (i.e. genus) described in the instant application at page 24, lines 15-23, and concludes that Sierra therefore anticipates the presently pending composition claims.

However, the test for inherency of a composition claim is not whether Applicant's specification describes a method genus when the cited reference describes a method species. If this basis of rejection is maintained, Applicants respectfully request that the Examiner provide guidance to any statutory, regulatory, or judicial authority for such a rule. Although the Examiner's analysis may in some aspects comport with a layman's usage of the word "inherent", it most certainly does not meet the legal definition of inherency.

In fact, the proper test for inherency requires the Action to show that the presently claimed degradation time **must** flow as a natural consequence from the technological constraints of Sierra. According to this test, as noted above, it is inappropriate to conclude that a degradation time of less than one year is inherent to Sierra's pulverized gelatin.

Sierra Not Shown To Disclose The Claimed Subunit Size

As recited in presently pending independent claims 1 and 34, the colloid can have a subunit size when fully hydrated in the range from 0.01 mm to 5 mm.

The Action at page 7 asserts that the process (i.e. species) described by Sierra reads on the process steps (i.e. genus) described in the instant application at page 24, lines 15-23, and concludes that Sierra therefore anticipates the presently pending composition claims. As noted above under the section titled "Second Alleged Basis For Inherency," this does not meet the legal definition of inherency. The Action is required to show that the presently claimed

subunit size **must** flow as a natural consequence from the technological constraints of Sierra. According to this test, a subunit size when fully hydrated in the range from 0.01 mm to 5 mm is not inherent to Sierra's pulverized gelatin.

Moreover, the Action at page 2 states that Sierra's lyophilized and pulverized particles are 20 to 150 microns. Yet these are dried particles. There is no teaching in Sierra of the size of a fully hydrated subunit as presently claimed. Thus Sierra fails to anticipate the presently claimed subunit size.

Sierra Not Shown To Disclose The Claimed Equilibrium Swell

As recited in presently pending independent claims 1 and 34, the colloid can have an equilibrium swell from 400% to 5000%.

The Action at page 7 asserts that the process (i.e. species) described by Sierra reads on the process steps (i.e. genus) described in the instant application at page 24, lines 15-23, and concludes that Sierra therefore anticipates the presently pending composition claims. As noted above under the section titled "Second Alleged Basis For Inherency," this does not meet the legal definition of inherency. The Action is requires to show that the presently claimed subunit size **must** flow as a natural consequence from the technological constraints of Sierra. According to this test, an equilibrium swell from 400% to 5000% is not inherent to Sierra's pulverized gelatin.

Based on the above, Sierra fails to teach or suggest each of the elements of presently pending independent claims 1 and 34, and therefore does not anticipate these claims. Claims 19-21, 23, 24, 28, and 29 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the novel combination of elements they recite. Claim 22 was previously canceled. Withdrawal of this rejection is respectfully requested.

Second Rejection Under 35 U.S.C. §102

¶2. Claims 1, 20-23, 25, 30, and 35 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 4,818,517 to Kwee et al. ["Kwee"]. This rejection is traversed.

Presently pending independent claims 1 and 35 recite a colloid that is substantially free from a free aqueous phase.

Kwee's Hydrogel Is Alleged To Contain Free Aqueous Phase

The Office Action alleges at page 3 that Kwee describes a composition that “does not contain any free aqueous phase *other than* the water that forms a part of the hydrogel” (Emphasis added). With this conditional phrase, the Examiner concludes that Kwee contains no free aqueous phase, subject to one qualification or exception. The exception is that a free aqueous phase (i.e. water) forms a part of the hydrogel. Thus the Examiner construes Kwee to describe a hydrogel that includes a free aqueous phase. For at least this reason, Applicants submit that Kwee does not anticipate independent claims 1 and 35, which include a colloid that is substantially free from a free aqueous phase.

Kwee's Hydrogel Contains Two Phases

The Office Action at page 8 alleges that “the disclosure of Kwee nowhere suggests that the hydrogel comprises two phases.” Applicants submit that claim 1 of Kwee in fact describes such a hydrogel, more specifically a two phase hydrogel having (1) a first phase including a water-insoluble polymer, and (2) a second phase including a water-soluble thickening agent. Because the polymer is *water-insoluble*, and is in the presence of a *water-soluble* thickening agent, there clearly are two different phases in Kwee's composition.

According to the Action, “The water-soluble thickener is present only to absorb the remaining water and it is very evident from the teachings of Kwee that the latter is not a part of the swollen polymer.” Applicants disagree with this interpretation.

Kwee, at col. 1, lines 35-40, reports that a composition that includes only the swellable polymer cannot be properly syringed because pressure forces water out of the gel or suspension. At col. 1, lines 45-48, Kwee reports that the presence of a thickening agent *in* the hydrogel improves syringeability. Thus, according to Kwee, the thickening agent is structurally integral to the hydrogel. It is this two-phase nature that imparts enhanced syringeability. In fact, claim 1 of Kwee reports that the thickening agent prevents separation of water from the hydrogel, in contrast to the Office Action's conclusion that the thickening absorbs water that is

separate from the hydrogel. If the thickening agent (water-soluble phase) were removed or separated from the polymer (water-insoluble phase), the result would be an unsyringeable hydrogel, according to Kwee.

Moreover, the Office Action's comments regarding the term "hydrogel" at page 9 are irrelevant because the term is not recited in the claims.

Thus, neither of Kwee's two different phases, either alone or in combination with one another, anticipate the presently claimed single phase aqueous colloid which is substantially free from a free aqueous phase.

Kwee Not Shown To Disclose The Claimed Subunit Size

As recited in presently pending independent claims 1 and 35, the colloid can have a subunit size when fully hydrated in the range from 0.01 mm to 5 mm. The Office Action provides no guidance as to where in Kwee this claim element can be found, either expressly or inherently.

Kwee Not Shown To Disclose The Claimed Degradation Rate

As recited in presently pending independent claims 1 and 35, the colloid can have an *in vivo* degradation time of less than one year.

The Action at page 3 asserts that the dextrin polymer (i.e. species) described by Kwee reads on the polysaccharide (i.e. genus) described in the instant application, and concludes that Kwee therefore anticipates the presently pending claims.

However, the test for inherency of a composition claim is not whether Applicant's specification describes a genus when the cited reference describes a species. If this basis of rejection is maintained, Applicants respectfully request that the Examiner provide guidance to any statutory, regulatory, or judicial authority for such a rule. Although the Examiner's analysis may in some aspects comport with a layman's usage of the word "inherent", it most certainly does not meet the legal definition of inherency.

In fact, the proper test for inherency requires the Action to show that the presently claimed degradation time *must* flow as a natural consequence from the technological constraints

of Kwee. According to this test, as noted above, it is inappropriate to conclude that a degradation time of less than one year is inherent to Kwee's dextrin.

Kwee Not Shown To Disclose The Claimed Equilibrium Swell

As recited in presently pending independent claims 1 and 35, the colloid can have an equilibrium swell from 400% to 5000%.

The Action at page 3 asserts that the dextrin polymer (i.e. species) described by Kwee reads on the polysaccharide (i.e. genus) described in the instant application, and concludes that Kwee therefore anticipates the presently pending claims.

However, the test for inherency of a composition claim is not whether Applicant's specification describes a genus when the cited reference describes a species. If this basis of rejection is maintained, Applicants respectfully request that the Examiner provide guidance to any statutory, regulatory, or judicial authority for such a rule. Although the Examiner's analysis may in some aspects comport with a layman's usage of the word "inherent", it most certainly does not meet the legal definition of inherency.

In fact, the proper test for inherency requires the Action to show that the presently claimed equilibrium swell **must** flow as a natural consequence from the technological constraints of Kwee. According to this test, as noted above, it is inappropriate to conclude that an equilibrium swell from 400% to 5000% is inherent to Kwee's dextrin.

First Rejection Under 35 U.S.C. §103

¶3. Claims 25-29 were rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 6,110,484 to Sierra et al. ["Sierra"]. This rejection is traversed.

MPEP 2143 requires that to establish a *prima facie* case of obviousness, among other things, the cited reference must teach or suggest all the claim elements. As noted above, Sierra fails to teach or suggest each and every element of presently pending independent claim 1. Claims 25-29 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the nonobvious combination of elements they recite. Withdrawal of this rejection is respectfully requested.

Second Rejection Under 35 U.S.C. §103

¶4. Claims 19, 24, 31, 32, and 36 were rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 4,818,517 to Kwee et al. [“Kwee”]. This rejection is traversed.

MPEP 2143 requires that to establish a *prima facie* case of obviousness, among other things, the cited reference must teach or suggest all the claim elements. As noted above, Kwee fails to teach or suggest each and every element of amended independent claim 1, and for many of the same reasons, Applicants submit that Kwee fails to teach or suggest each and every element of presently pending independent claim 36, which recites a single phase aqueous colloid that is substantially free from a free aqueous phase.

Claims 19, 24, 31, and 32 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the nonobvious combination of elements they recite. Withdrawal of this rejection is respectfully requested.

Third Rejection Under 35 U.S.C. §103

¶5. Claims 26-29, and 33 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 4,818,517 to Kwee et al. in view of U.S. Patent No. 4,837,285 to Berg et al. [“Berg”]. Applicants traverse this rejection.

MPEP 2143 requires that to establish a *prima facie* case of obviousness, among other things, the cited references when combined must teach or suggest all the claim elements.

As noted above, Kwee fails to teach or suggest each and every element of amended independent claim 1. Berg fails to remedy the deficiencies of Kwee, because Berg fails to teach or disclose a single phase aqueous colloid which is substantially free from a free aqueous phase as presently claimed.

Claims 26-29 and 33 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the nonobvious combination of elements they recite. Withdrawal of this rejection is respectfully requested.

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Examining Group 1615

PATENT

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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